

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 04-1/23 on April 14, 2023

N	Trade name	Common name of the active substance	Pharmaceutical form	Strength and packaging, presentation	All manufacturing sites involved in the medicinal product manufacturing process (name, location)	Country	Registration certificate holder (name, location)	Country	Legal status for supply	Conclusion number and date
1	Jadenu	deferasirox	tablets film-coated	180mg; (30/3x10/) in blister	Sandoz S.R.L., str. Livezeni nr. 7A, 540472, Targu Mures	Romania	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	21340 1 4.04.2023
2	Jadenu	deferasirox	tablets film-coated	360mg; (30/3x10/) in blister	Sandoz S.R.L., str. Livezeni nr. 7A, 540472, Targu Mures	Romania	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	21341 14.04.2023
3	Curosurf	poractant alfa	suspension endotracheal	80mg/ml; glass vial 1,5ml	Chiesi Farmaceutici S.p.A., Via San Leonardo 96, Parma (PR), 43122	Italy	Chiesi Pharmaceuticals GmbH, Gonzagagasse 16/16, 1010 Wien	Austria	PoM	21342 14.04.2023

LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 04-1/23 on April 14, 2023

N	Trade name	Common name of the active substance	Pharmaceutical form	Strength and packaging, presentation	All manufacturing sites involved in the medicinal product manufacturing process (name, location)	Country	Registration certificate holder (name, location)	Country	Legal status for supply	Conclusion number and date
1	Devit 50000	colecalfiferol	tablets film-coated	1,25mg (50 000IU); (8/1x8/) in blister, (15/1x15/) in blister	Quest Vitamins Middle East Fze, Jebel- Ali Free Zone, P.O. Box 17836, Dubai	United Arab Emirates	Quest Vitamins Middle East Fze, Jebel- Ali Free Zone, P.O. Box 17836, Dubai	United Arab Emirates	PoM	21304 14.04.2023
2	Aspicor 100	acetylsalicylic acid	tablets gastro-resistant	100mg; (1000/100x10/) in blister	Coral Laboratories Ltd., Plot No. 57/1 (16), Bhenslore, Dunetha, Nani Daman 396 210	India	Coral Laboratories Ltd., 503, Dalamal House, 5th floor, J.B. Marg, Nariman Point, Mumbai 400 021	India	OTC	21305 14.04.2023
3	Vizoptin	tetryzoline (tetryzoline hydrochloride)	drops eye (solution)	0,5mg/ml; 15ml plastic vial-dropper	Rompharm Company SRL, Eroilor Str., No. 1A, Otopeni city, Ilfov county, 075100, buildings Rompharm 1 and Rompharm 2	Romania	LLC Rompharm Company Georgia, Vake-Saburtalo District, G. Saakadze downhill, N8, office N7a, Tbilisi	Georgia	OTC	21306 14.04.2023
4	Rovastat	rosuvastatin (rosuvastatin calcium)	tablets film-coated	10mg; (28/4x7/) in blister	Adamed Pharma S.A., 5, Marszalka Jozefa Pilsudskiego St., 95-200 Pabianice- quality control, batch releaser, Adamed Pharma S.A., 33, Szkolna St., 95-054 Ksawerow, Poland- bulk manufacturer, packager	Poland	Adamed Pharma S.A., 6A, Pienkow, Mariana Adamkiewiczza St., 05-152 Czosnow	Poland	PoM	21307 14.04.2023

5	Rovastat	rosuvastatin (rosuvastatin calcium)	tablets film-coated	20mg; (28/4x7) in blister	Adamed Pharma S.A., 5, Marszalka Jozefa Pilsudskiego St., 95-200 Pabianice- quality control, batch releaser, Adamed Pharma S.A., 33, Szkolna St., 95-054 Ksawerow, Poland- bulk manufacturer, packager	Poland	Adamed Pharma S.A., 6A, Pienkow, Mariana Adamkiewiczza St., 05- 152 Czosnow	Poland	PoM	21308 14.04.2023
6	Ceftriaxone for injection	ceftriaxone (ceftriaxone sodium)	powder for solution for i/m and i/v injection	1000mg; (10) glass vials	Reyoung Pharmaceutical Co. Ltd, No.1 Ruiyang road, Yiyuan county, Shandong Province	China	Reyoung Pharmaceutical Co. Ltd, No.1 Ruiyang road, Yiyuan county, Shandong Province	China	PoM	21309 14.04.2023
7	Pergoveris	folitropin alfa, lutropin alfa	powder lyophilized for solution for s/c injection	150IU+75IU; (1) glass vial and (1) solvent in vial 1ml, (3) glass vials and (3) solvent in vials 1ml, (10) glass vials and (10) solvent in vials 1ml	Merck Serono S.p.A., Via delle Magnolie 15, 70026 Modugno (BA)- batch releaser , Merck Serono S.A., Succursale d Aubonne, Zone Industrielle de l Ouriettaz, 1170 Aubonne, Switzerland-bulk manufacturer, packager	Italy	Merck LLC, Valovaya Str. 35, 115054 Moscow	Russia	PoM	21310 14.04.2023
8	Tabex	cytisine	tablets film-coated	1,5mg; (100/5x20/) in blister	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	OTC	21311 14.04.2023

9	MIG 400	ibuprofen	tablets film-coated	400mg; (10/1x10/) in blister, (20/2x10/) in blister, (30/3x10/) in blister, (50/5x10/) in blister	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin- packager, quality control (microbiological), batch releaser, Berlin-Chemie AG, Tempelhofer Weg 83, 12347 Berlin, Germany- bulk manufacturer, 1.Berlin-Chemie AG, Tempelhofer Weg 83, 12347 Berlin, Germany, 2.Berlin-Chemie AG, Tempelhofer Weg 83, 12347 Berlin, Germany- quality control (physicochemical)	Germany	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin	Germany	OTC	21312 14.04.2023
10	Almagel	aluminium hydroxide, magnesium hydroxide	suspension oral	436mg/ml+70mg/ml; 170ml glass bottle and measuring spoon 5ml, 170ml plastic bottle and measuring spoon 5ml, (10) sachets 10ml, (20) sachets 10ml	Balkanpharma-Troyan AD, Krayrechna Str. N1, 5600, Troyan	Bulgaria	Balkanpharma-Troyan AD, Krayrechna Str. N1, 5600, Troyan	Bulgaria	OTC	21313 14.04.2023
11	Omacor	omega-3 triglycerides	capsules soft	1000mg; (28) in plastic container	Abbott Laboratories GmbH, Justus-von-Liebig-Strasse 33, 31535 Neustadt- quality control, batch releaser, Patheon Softgels B.V., De Posthoornstraat 7, 5048 AS Tilburg, the Netherlands- bulk manufacturer, GMPack ApS, Plastvaenget 9, 9560 Hadsund, Denmark- packager	Germany	Abbott Laboratories GmbH, Freundallee 9A, 30173 Hannover	Germany	PoM	21314 14.04.2023

12	Bepanthen Plus	dexpanthenol, chlorhexidine (chlorhexidine dihydrochloride)	cream for external use	50mg/g+5mg/g; 30g aluminium tube	GP Grenzach Produktions GmbH, Emil-Barell-Strasse 7, D-79639 Grenzach- Wyhlen	Germany	Bayer Consumer Care AG, Peter Merian- Strasse 84, 4052 Basel	Switzerland	OTC	21315 14.04.2023
13	Actrapid	insulin human (recombinant DNA)	solution for injection	100IU/ml; glass vial 10ml	Novo Nordisk Production SAS, 45 avenue d' Orleans, F-28000, Chartres	France	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	PoM	21316 14.04.2023
14	Amoxil	amoxicillin (amoxicillin trihydrate)	tablets	250mg; (20/2x10/) in blister	Kievmedpreparat PJSC, 01032, Kyiv, Saksaganskogo street, 139	Ukraine	Kievmedpreparat PJSC, 01032, Kyiv, Saksaganskogo street, 139	Ukraine	PoM	21317 14.04.2023
15	Amoxil	amoxicillin (amoxicillin trihydrate)	tablets	500mg; (20/2x10/) in blister	Kievmedpreparat PJSC, 01032, Kyiv, Saksaganskogo street, 139	Ukraine	Kievmedpreparat PJSC, 01032, Kyiv, Saksaganskogo street, 139	Ukraine	PoM	21318 14.04.2023
16	Nucleo CMP Forte	cytidine-5-disodium monophosphate + (uridine-5-trisodium triphosphate, uridine-5-disodium diphosphate, uridine-5-disodium monophosphate)	capsules	5mg+3mg; (30/2x15/) in blister	Ferrer International, S.A., Joan Buscalla,1-9 08173 Sant Cugat del Valles, Barcelona	Spain	Ferrer International, S.A., Gran Via Carlos III, 94, 08028, Barcelona	Spain	OTC	21319 14.04.2023
17	Inestom	levocarnitine	solution oral	100mg/ml; (10) glass vials 10ml	Help S.A., Pedini Ioanninon, Ioannina, 45500	Greece	Help S.A., 10 Valaoritou str., GR 14452 Metamorfosi, Attiki	Greece	PoM	21320 14.04.2023
18	Inestom	levocarnitine	solution for injection	200mg/ml; (5) ampoules 5ml	Help S.A., Pedini Ioanninon, Ioannina, 45500	Greece	Help S.A., 10 Valaoritou str., GR 14452 Metamorphosis, Attica	Greece	PoM	21321 14.04.2023
19	Dramina	dimenhydrinate	tablets	50mg; (5/1x5/) in blister, (10/1x10/) in blister	JADRAN-GALENSKI LABORATORIJ d.d., Svilno 20, 51000 Rijeka	Croatia	JADRAN-GALENSKI LABORATORIJ d.d., Svilno 20, 51000 Rijeka	Croatia	OTC	21322 14.04.2023

20	Progestogel	progesterone	gel for external use	10mg/g; 80g aluminium tube and dosator	Delpharm Drogenbos SA, Groot-Bijgaardenstraat, 128-1620, Drogenbos	Belgium	Besins Healthcare Benelux, Avenue Louise 287, 1050 Brussels	Belgium	PoM	21323 14.04.2023
21	Betamaks	sulpiride	tablets	50mg; (30/3x10/) in blister	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	PoM	21324 14.04.2023
22	Betamaks	sulpiride	tablets	100mg; (30/3x10/) in blister	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	PoM	21325 14.04.2023
23	Betamaks	sulpiride	tablets	200mg; (30/3x10/) in blister	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	PoM	21326 14.04.2023
24	Fervex	paracetamol, ascorbic acid, pheniramine (pheniramine maleate)	powder for oral solution with raspberry flavour and sugar	500mg+200mg+25mg; (8) sachets 12,75g	UPSA SAS, 979, Avenue des Pyrenees, 47520 Le Passage	France	UPSA SAS, 3, rue Joseph Monier92500 Rueil-Malmaison	France	OTC	21327 14.04.2023
25	Fervex	paracetamol, ascorbic acid, pheniramine (pheniramine maleate)	powder for oral solution with lemon flavour and sugar	500mg+200mg+25mg; (8) sachets 13,1g	UPSA SAS, 979, Avenue des Pyrenees, 47520 Le Passage	France	UPSA SAS, 3, rue Joseph Monier-92500 Rueil-Malmaison	France	OTC	21328 14.04.2023
26	Diclo-Denk 75 Injection	diclofenac (diclofenac sodium)	solution for injection	25mg/ml; (10) ampoules 3ml	Haupt Pharma Wulfing GmbH, Bethelner Landstrasse 18, Gronau/Leine 31028	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Munchen	Germany	PoM	21329 14.04.2023
27	Anti-Acne	salicylic acid, sulfur, zinc oxide	suspension for external use	20mg/ml+50mg/ml+150mg/ml; 30ml glass bottle	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	OTC	21330 14.04.2023
28	Nicotinic acid-Darnitsa	nicotinic acid	solution for injection	10mg/ml; (10/2x5/) ampoules 1ml in blister	PrJSC "Pharmaceutical firm "Darnitsa", 02093, Kyiv, Boryspilska Str.,13	Ukraine	PrJSC "Pharmaceutical firm "Darnitsa", 02093, Kyiv, Boryspilska Str.,13	Ukraine	PoM	21331 14.04.2023

29	Doxorubicin hydrochloride	doxorubicin (doxorubicin hydrochloride)	lyophilisate for solution for i/v injection	10mg; (1) glass vial 10ml, (40) glass vials 10ml	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30- quality control, batch releaser, Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30, No2, Republic of Belarus- bulk manufacturer, packager	Republic of Belarus	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30,	Republic of Belarus	PoM	21332 14.04.2023
30	Lorista H 100	losartan (losartan potassium), hydrochlorothiazide	tablets film-coated	100mg+12,5mg; (28/2x14/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	21333 14.04.2023
31	Ovitrelle	choriogonadotropin alfa	solution for s/c injection	250mcg/0,5ml; (1) glass pre-filled syringe with needle in plastic pack	Merck Serono S.p.A., Via delle Magnolie 15, 70026 Modugno (BA)	Italy	Merck LLC, 35 Valovaya Street, Moscow 115054	Russia	PoM	21334 14.04.2023
32	Codelac Broncho with thyme	ambroxol (ambroxol hydrochloride), glycyrrhizic acid trisodium (sodium glycyrrhizinate), thyme extract	elixir	10mg/5ml+30mg/5ml+500mg/5ml; 100ml glass bottle and measuring spoon, 200ml glass bottle and measuring spoon	Pharmstandard-Leksredstva JSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	JSC "OTCPharm", Testovskaya street, 10, flr.12, room II, off. 29, Moscow 123112	Russia	OTC	21335 14.04.2023
33	Tulosin	tamsulosin (tamsulosin hydrochloride)	capsules modified-release	0,4mg; (10/1x10/) in blister, (30/3x10/) in blister	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38	Hungary	PoM	21336 14.04.2023

LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 04-1/23
on April 14, 2023

N	Trade name	Common name of the active substance	Pharmaceutical form	Strength and packaging, presentation	All manufacturing sites involved in the medicinal product manufacturing process (name, location)	Country	Registration certificate holder (name, location)	Country	Legal status for supply	Conclusion number and date
1	Dolgit	ibuprofen	gel for external use	5g/100g; 20g aluminium tube, 50g aluminium tube, 100g aluminium tube	Dolorgiet GmbH & Co.KG, Otto-von-Guericke-Strasse 1, 53757 Sankt Augustin- bulk manufacturer, packager, batch releaser, Dolorgiet GmbH & Co.KG, Otto-von-Guericke-Strasse 1, 53757 Sankt Augustin, Germany, 2.GBA Pharma GmbH, Anna-Sigmund-Strasse 82061 Neuried, Germany- quality control (physicochemical), BAV INSTITUT fur Hygiene und Qualitätssicherung GmbH ,Hanns-Martin-Schleyer-Str. 25, D-77656 Offenburg, Germany- quality control (microbiological)	Germany	Dolorgiet GmbH & Co.KG, Otto-von-Guericke Str. 1, 53757 Sankt Augustin	Germany	OTC	20836/1/1 14.04.2023
2	Analgin	metamizole (metamizole sodium)	solution for i/v and i/m injection	500mg/ml; (10) ampules 2ml CAMA, (10) ampules 2ml label banderol, (10) ampules 2ml dividella	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64, No10/1, No11/1, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	PoM	19759/2/1 14.04.2023

3	Pregabalin Canon	pregabalin	capsules	75mg; (14/2x7/) in blister, (14/1x14/) in blister	CJSC Canonpharma production, 105B, 11, Zarechnaya street, Schelkovo city, Schelkovo urban district, Moscow region, 141100- quality control, batch releaser, CJSC Canonpharma production, 105, Zarechnaya street, Schelkovo city, Schelkovo urban district, Moscow region, 141100, Russia- bulk manufacturer, packager	Russia	CJSC Canonpharma production, 105, Zarechnaya street, Schelkovo city, Moscow region, 141100	Russia	PoM	19835/1/1 14.04.2023
4	Pregabalin Canon	pregabalin	capsules	150mg; (14/2x7/) in blister, (14/1x14/) in blister	CJSC Canonpharma production, 105B, 11, Zarechnaya street, Schelkovo city, Schelkovo urban district, Moscow region, 141100- quality control, batch releaser, CJSC Canonpharma production, 105, Zarechnaya street, Schelkovo city, Schelkovo urban district, Moscow region, 141100, Russia- bulk manufacturer, packager	Russia	CJSC Canonpharma production, 105, Zarechnaya street, Schelkovo city, Moscow region, 141100	Russia	PoM	19836/1/1 14.04.2023
5	Pregabalin Canon	pregabalin	capsules	300mg; (14/2x7/) in blister, (14/1x14/) in blister	CJSC Canonpharma production, 105B, 11, Zarechnaya street, Schelkovo city, Schelkovo urban district, Moscow region, 141100- quality control, batch releaser, CJSC Canonpharma production, 105, Zarechnaya street, Schelkovo city, Schelkovo urban district, Moscow region, 141100, Russia- bulk manufacturer, packager	Russia	CJSC Canonpharma production, 105, Zarechnaya street, Schelkovo city, Moscow region, 141100	Russia	PoM	19837/1/1 14.04.2023

LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 04-/23
on April 14, 2023

N	Trade name	Common name of the active substance	Pharmaceutical form	Strength and packaging, presentation	All manufacturing sites involved in the medicinal product manufacturing process (name, location)	Country	Registration certificate holder (name, location)	Country	Legal status for supply	Conclusion number and date
1	Trimedat forte	trimebutine	tablets prolonged-release film-coated	300mg; (20/2x10) in blister, (60/6x10) in blister	Valenta Pharm JSC, 141101, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	Valenta Pharm JSC, 141101, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	PoM	19333/3/1 14.04.2023
2	Enap	enalaprilat	solution for injection	1,25mg/ml; (5) ampoules 1ml, in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	16949/2 14.04.2023
3	Sinaflan	fluocinolone acetonide	ointment	0,25mg/g; 10g and 15g aluminium tube, 10g and 15g plastic laminated tube	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	PoM	17605/2 14.04.2023
4	Grani-Denk 1mg/ml	granisetron (granisetron hydrochloride)	concentrate for solution for injection/infusion	1mg/ml; (5) ampoules 1ml	Solpharm Pharmazeutische Erzeugnisse GmbH, Industriestr. 3, 34212, Melsungen	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Munchen	Germany	PoM	18995/1 14.04.2023
5	Grani-Denk 1mg/ml	granisetron (granisetron hydrochloride)	concentrate for solution for injection/infusion	1mg/ml; (5) ampoules 3ml	Solpharm Pharmazeutische Erzeugnisse GmbH, Industriestr. 3, 34212, Melsungen	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Munchen	Germany	PoM	18996/1 14.04.2023

6	Dalacin	clindamycin (clindamycin hydrochloride)	capsules	150mg; (16/2x8/) in blister	Fareva Amboise, Zone Industrielle, 29 route des Industries, 37530 Poce-sur-Cisse	France	Pfizer H.C.P. Corporation, 235, East 42nd Street, New York 10017	USA	PoM	18181/4 14.04.2023
7	Dalacin	clindamycin (clindamycin hydrochloride)	capsules	300mg; (16/2x8/) in blister	Fareva Amboise, Zone Industrielle, 29 route des Industries, 37530 Poce-sur-Cisse	France	Pfizer H.C.P. Corporation, 235, East 42nd Street, New York 10017	USA	PoM	18182/3 14.04.2023
8	Brilinta	ticagrelor	tablets film-coated	90mg; (56/4x14/) in blister	AstraZeneca AB Gartunavagen, Sodertalje, SE-15185	Sweden	AstraZeneca AB, Sodertalje, SE-15185	Sweden	PoM	20062/1 14.04.2023
9	Panzynorm forte 20 000	pancreatin (lipase, amylase, protease)	tablets gastro-resistant, coated	20000U+12000U+900U; (10/1x10/) and (30/3x10/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	OTC	18743/1 14.04.2023
10	Stresam	etifoxine (etifoxine hydrochloride)	capsules	50mg; (60/3x20/) in blister	Biocodex, 1 avenue Blaise Pascal, 60000 Beauvais	France	Biocodex, 7 avenue Gallieni 94250 Gentilly	France	PoM	17646/3 14.04.2023
11	Parlazin	cetirizine (cetirizine dihydrochloride)	drops oral	10mg/ml; 20ml glass vial with dropper	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38	Hungary	OTC	19699/1 14.04.2023
12	Kisqali	ribociclib(ribociclib succinate)	tablets film-coated	200mg; (21/1x21/) in blister, (63/3x21/) in blister	Novartis Pharma Produktions GmbH, Oeflinger Strasse 44, 79664 Wehr -batch releaser, packager, Novartis Singapore Pharmaceutical Manufacturing Pte. Ltd., 10 Tuas Bay Lane, 637461 Singapore, Singapore-bulk manufacturer	Germany	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	18535/7/1 14.04.2023

13	KISQALI	ribociclib (ribociclib succinate)	tablets film-coated	200mg; (21/1x21/) in blister, (63/3x21/) in blister	Novartis Pharma Stein AG, Schaffhauserstrasse, Stein AG, 4332- packager, batch releaser, Novartis Singapore Pharmaceutical Manufacturing Pte. Ltd., 10 Tuas Bay Lane, 637461 Singapore, Singapore- bulk manufacturer, quality control	Switzerland	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	20278/2 14.04.2023
14	Dexalgin inject	dexketoprofen (dexketoprofen trometamol)	solution for injection/ infusion	25mg/ml; (1) ampoules 2ml, (5) ampoules 2ml, (10) ampoules 2ml	A. Menarini Manufacturing Logistics and Services S.r.l., Via Sette Santi, 3-50131 Florence	Italy	Menarini International Operations Luxembourg S.A.,1, avenue de la Gare, 1611	Luxembourg	PoM	18616/4 14.04.2023
15	Omacor	omega-3 triglycerides	capsules soft	1000mg; (28) in plastic container	Abbott Laboratories GmbH, Justus-von-Liebig-Strasse 33, 31535 Neustadt - batch releaser, Patheon Softgels B.V., De Posthoornstraat 7, 5048 AS Tilburg, the Netherlands- bulk manufacturer, GMPack ApS, Plastvaenget 9, 9560 Hadsund, Denmark- packager	Germany	Abbott Laboratories GmbH, Freundallee 9A, 30173 Hannover	Germany	PoM	17500/3 14.04.2023
16	Dramina	dimenhydrinate	tablets	50mg; (5/1x5/), (10/1x10/) in blister	JADRAN-GALENSKI LABORATORIJ d.d., Svilno 20, 51000 Rijeka	Croatia	JADRAN-GALENSKI LABORATORIJ d.d., Svilno 20, 51000 Rijeka	Croatia	OTC	17101/2 14.04.2023
17	Aspicor 100	acetylsalicylic acid	tablets gastro-resistant	100mg; (1000/100x10/) in blister	Coral Laboratories Ltd., Plot No. 57/1 (16), Bhenslore, Dunetha, Nani Daman 396 210	India	Coral Laboratories Ltd., 503, Dalamal House, 5th floor, J.B. Marg, Nariman Point, Mumbai 400 021	India	OTC	16387/1 14.04.2023
18	Eksportal	lactitol monohydrate	powder for oral solution	5g, (6/3x2/) sachets 5g (6) sachets 5g	PharmVilar LLC SPA, Communiststreet 115, bldg., Maloyaroslavets, Kaluga region, Maloyaroslavetsky district	Russia	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	OTC	19947/3/1 14.04.2023

19	Eksportal	lactitol monohydrate	powder for oral solution	10g, (10/5x2/) sachets 10g, (20/10x2/) sachets 10g, (10) sachets 10g, (20) sachets 10g	PharmVilar LLC SPA, Communiststreet 115, bldg., Maloyaroslavets, Kaluga region, Maloyaroslavetsky district	Russia	Valenta Pharm JSC, 141108, Moscow Region, Shchelkovo, Fabrichnaya St., 2,	Russia	OTC	19946/3/1 14.04.2023
20	Xarelto	rivaroxaban	tablets film-coated	2,5mg; (56/4x14/) in blister	Bayer AG, Kaiser-Wilhelm-Allee, 51368 Leverkusen, Germany	Germany	Bayer AG, Kaiser-Wilhelm-Allee, 1, 51373 Leverkusen	Germany	PoM	19035/3 14.04.2023
21	Yarina	drospirenone, ethinylestradiol	tablets film-coated	3mg+30mcg; (21/1x21/) in blister	Bayer AG, Muellerstrasse 178, 13353, Berlin- packager, quality control, batch releaser, Bayer Weimar GmbH und Co. KG, Doebereinerstrasse 20, Weimar, Thueringen, 99427, Germany- bulk manufacturer	Germany	Bayer AG, Kaiser-Wilhelm-Allee 1, 51373 Leverkusen	Germany	PoM	19185/3 14.04.2023
22	Dolgit	ibuprofen	cream for external use	5g/100g; 20g aluminium tube, 50g aluminium tube, 100g aluminium tube	Dologiet GmbH & Co.KG, Otto-von-Guericke-Strasse 1, 53757 Sankt Augustin- bulk manufacturer, packager, batch releaser, Dologiet GmbH & Co.KG, Otto-von-Guericke-Strasse 1, 53757 Sankt Augustin, Germany, 2.GBA Pharma GmbH, Anna-Sigmund-Strasse 82061 Neuried, Germany- quality control (physicochemical), BAV INSTITUT fur Hygiene und Qualitatssicherung GmbH ,Hanns-Martin-Schleyer-Str. 25, D-77656 Offenburg, Germany- quality control (microbiological)	Germany	Dologiet GmbH & Co.KG, Otto-von-Guericke Str. 1, 53757 Sankt Augustin	Germany	OTC	20835/1 14.04.2023

23	Naratriptan	naratriptan (naratriptan hydrochloride)	tablets film-coated	2,5mg; (2/1x2/) and (6/1x6/) in blister	Chanelle Medical Unlimited Company, Dublin Road Loughrea, Co. Galway- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Complete Laboratory Solutions, Units 3A & 8 Ida Small Business Centre Tuam Road, Galway, H91 H520, Ireland- quality control (microbiological)	Ireland	ARGO-PHARM LLC, 13/9 Sundukyan str., 0012 Yerevan	Republic of Armenia	PoM	17800/1 14.04.2023
24	Meloxicam STADA	meloxicam	tablets	15mg; (20/2x10/) in blister	Hemofarm LLC, 249032, Obninsk, Kaluga Region, 62 Kievskoye highway	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	PoM	17728/2 14.04.2023
25	Trozamil	azithromycin (azithromycin dihydrate)	tablets film-coated	500mg; (3) in blister	Special Products Line S.p.A., Via Fratta Rotonda Vado Largo, I-03012 Anagni (FR)	Italy	So.Se.Pharm. S.r.l., Via dei Castelli Romani 22, 00071 Pomezia (Rome)	Italy	PoM	17991/2 14.04.2023
26	Jakavi	ruxolitinib (ruxolitinib phosphate)	tablets	5mg; (56/4x14) in blister	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	18505/9/1 14.04.2023
27	Jakavi	ruxolitinib (ruxolitinib phosphate)	tablets	15mg; (56/4x14) in blister	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	18506/9/1 14.04.2023
28	Catafast	diclofenac (diclofenac potassium)	powder for oral solution	50mg; (3) and (21) sachets	Mipharm S.p.A., VIA Bernardo Quaranta, 12, 20141 Milano (MI)	Italy	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	18035/4 14.04.2023
29	Diflucan	fluconazole	capsules	50mg; (7/1x7/) in blister	Fareva Amboise, Zone Industrielle, 29 route des Industries, 37530 Poce-sur-Cisse	France	Pfizer H.C.P. Corporation, 235, East 42nd street New York 10017	USA	PoM	18201/7 14.04.2023

30	Diflucan	fluconazole	capsules	150mg; (1) blister	Fareva Amboise, Zone Industrielle, 29 route des Industries, 37530 Poce-sur-Cisse	France	Pfizer H.C.P. Corporation, 235, East 42nd street New York 10017	USA	PoM	18202/7 14.04.2023
31	Diflucan	fluconazole	solution for i/v infusion	2mg/ml; glass vial 50ml	Fareva Amboise, Zone Industrielle, 29 route des Industries, 37530 Poce-sur-Cisse	France	Pfizer H.C.P. Corporation, 235, East 42nd street New York 10017	USA	PoM	18203/4 14.04.2023
32	Salbutamol	salbutamol (salbutamol sulfate)	suspension, pressurised inhalation	100mcg/dose; aluminium container with inhaler (200 doses)	Glaxo Wellcome Production, Zone Industrielle N 2, 23 Rue Lavoisier, 27000 Evreux	France	Laboratoire GlaxoSmithKline, 100, route de Versailles, 78163 Marly-Le-Roi cedex,	France	PoM	19038/1 14.04.2023
33	Amoxil	amoxicillin (amoxicillin trihydrate)	tablets	250mg; (20/2x10/) in blister	Kievmedpreparat PJSC, 01032, Kiev, Saksaganskogo street, 139	Ukraine	Kievmedpreparat PJSC, 01032, Kiev, Saksaganskogo street, 139	Ukraine	PoM	17215/1 14.04.2023
34	Fervex	paracetamol, ascorbic acid, pheniramine (pheniramine maleate)	powder for oral solution with raspberry flavour and sugar	500mg+200mg+25mg; (8) sachets 12,75g	UPSA SAS, 979, Avenue des Pyrenees, 47520 Le Passage	France	UPSA SAS, 3, rue Joseph Monier- 92500 Rueil- Malmaison	France	OTC	17479/2 14.04.2023
35	Diclo-Denk 75 Injection	diclofenac (diclofenac sodium)	solution for injection	25mg/ml; (10) ampoules 3ml	Haupt Pharma Wulfing GmbH, Bethelner Landstrasse 18, Gronau/Leine 31028	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Munchen	Germany	PoM	17460/4 14.04.2023
36	Winch	fluconazole	capsules hard	150mg; (2) in blister	LABORATORIO FARMACEUTICO C.T. S.R.L., VIA DANTE ALIGHIERI, 71-18038 SANREMO (IM)	Italy	So.Se. Pharm S.r.l., Via dei Castelli Romani 22, 00040 Pomezia (Rome)	Italy	PoM	17584/1 14.04.2023

37	Fervex	paracetamol, ascorbic acid, pheniramine (pheniramine maleate)	powder for oral solution with lemon flavour and sugar	500mg+200mg+25mg; (8) sachets 13,1g	UPSA SAS, 979, Avenue des Pyrenees, 47520 Le Passage	France	UPSA SAS, 3, rue Joseph Monier- 92500 Rueil- Malmaison	France	OTC	17478/2 14.04.2023
38	Anti-Acne	salicylic acid, sulfur, zinc oxide	suspension topical	20mg/ml+50mg/ml+150mg/ml; 30ml glass bottle	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	OTC	17749/1 14.04.2023
39	Amelotex	meloxicam	tablets	15mg; (20/2x10/) in blister	SotexPharmFirm” CJSC, Bld. 10, 11, 12, village Belikovo, rural settlement Bereznyakovskoe, Sergiev-Posad municipal district, Moscow Region, 141345-secondary packager, batch releaser, Replek Farm Ltd.-Skopje, 188 str. Kozle, 1000 Skopje, Macedonia-bulk manufacturer, primary packager	Russia	“Sotex”PharmFirm” CJSC, Bld. 11, village Belikovo, rural settlement Bereznyakovskoe, Sergiev-Posad municipal district, Moscow Region, 141345	Russia	PoM	17107/2/1 14.04.2023
40	Magne B6	magnesium lactate dihydrate, pyridoxine hydrochloride	tablets coated	470mg+5mg; (60/3x20/) in blister	Chinoin Pharmaceutical and Chemical Works Private Co. Ltd., 2112 Veresegyhaz, Levai u. 5	Hungary	Chinoin Pharmaceutical and Chemical Works Private Co. Ltd., 2112 Veresegyhaz, Levai u. 5	Hungary	OTC	20826/1 14.04.2023
41	Champix	varenicline (varenicline tartrate)	tablets film-coated	0,5mg/1mg; (11/1x11/) (0,5mg) in blister and (14/1x14/) (1mg) in blister	Pfizer Manufacturing Deutschland GmbH, Betriebsstette Freiburg, Mooswaldallee 1, 79090 Frieburg- packager, batch releaser, Pfizer Italia S.r.L., Localita Marino del Tronto, 63100 Ascoli Piceno, Italy-bulk manufacturer, quality control	Germany	Pfizer H.C.P. Corporation, 235, East 42nd Street, New York 10017	USA	PoM	20998/1 14.04.2023

42	Champix	varenicline (varenicline tartrate)	tablets film-coated	1mg; (28/4x7/) in blister	Pfizer Manufacturing Deutschland GmbH, Betriebsstatte Freiburg, Mooswaldallee 1, 79090 Frieburg- packager, batch releaser, Pfizer Italia S.r.L., Localita Marino del Tronto, 63100 Ascoli Piceno, Italy- bulk manufacturer, quality control	Germany	Pfizer H.C.P. Corporation, 235, East 42nd Street, New York 10017	USA	PoM	20999/1 14.04.2023
43	Mertenil	rosuvastatin (rosuvastatin calcium)	tablets film-coated	5mg; (30/3x10/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	19808/2 14.04.2023
44	Mertenil	rosuvastatin (rosuvastatin calcium)	tablets film-coated	10mg; (30/3x10/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	19809/2 14.04.2023
45	Mertenil	rosuvastatin (rosuvastatin calcium)	tablets film-coated	20mg; (30/3x10/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	19810/2 14.04.2023
46	Diprospan	betamethasone (betamethasone dipropionate), betamethasone (betamethasone sodium phosphate)	suspension for injection	5mg/ml+2mg/ml; (5) ampoules 1ml	Schering-Plough Labo N.V., Industriepark 30, Heist-op- den-Berg, 2220	Belgium	Organon Central East GmbH, Weystrasse 20, 6006 Luzern	Switzerland	PoM	19021/3/1 14.04.2023
47	Tulosin	tamsulosin (tamsulosin hydrochloride)	capsules modified-release	0,4mg; (10/1x10/) and (30/3x10/) in blister	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38	Hungary	PoM	17587/3 14.04.2023
48	Codelac Broncho with thyme	ambroxol (ambroxol hydrochloride), glycyrrhizic acid trisodium (sodium glycyrrhizinate), thyme extract	elixir	10mg/5ml+30mg/5ml+ 500mg/5ml; 100ml and 200ml glass bottle and measuring spoon	Pharmstandard-Leksredstva JSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	JSC "OTCPharm", Testovskaya street, 10, fr.12, room II, off. 29, Moscow 123112	Russia	OTC	17290/4/3 14.04.2023

LIST

of the variations under the EAEU procedure not requiring reformulation of registration certificate approved by the Center according to the meeting
decision N 04-1/23 on April 14, 2023

N	Trade name	Common name of the active substance	Pharmaceutical form	Strength and packaging, presentation	All manufacturing sites involved in the medicinal product manufacturing process (name, location)	Country	Registration certificate holder (name, location)	Country	Legal status for supply	Conclusion number and date
1	Preductal OD	trimetazidine (trimetazidine dihydrochloride)	capsules prolonged-release	80mg; (30/3x10/) in blister, (60/6x10/) in blister	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	000215 14.04.2023